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10/825,434

04/16/2004

Joseph Levy

LEVY=18A

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,434	Applicant(s) LEVY ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-6,8,9,11,12,14,15,17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,10,13 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/799,251.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Preliminary Amendment and Information Disclosure Statement (IDS), both filed 04/16/04 and the Response to Restriction/Election Requirement filed 01/23/08 is acknowledged.

Applicant's election with traverse of Group II (method for reducing undesirable side effects) and Election of Species (c) (mixture of lycopene, phytoene & phytofluene) in the reply filed on 01/23/08 is acknowledged. The traversal is on the ground(s) that "The PTO has not demonstrated different classification for Groups II, III and IV, and it appears that a search for the elected Group II claims would encompass the claims for presently non-elected Groups III and IV". This is not found persuasive because as stated in the Restriction/Election requirement, the different groups entail different methods of treating and methods of administration and would thus require distinct process steps for each method group being claimed. The different methods claimed are capable of supporting a separate patent within the art, as they have different issues with regards to patentability and enablement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 8, 9, 11, 12, 14, 15, 17 and 18 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/23/08.

Claims 7, 10, 13 and 16 are being examined in this action. Claims 1-6, 8, 9, 11, 12, 14, 15, 17 and 18 have been withdrawn (non-elected invention). Claims 7, 10, 13 and 16 are rejected.

* * * * *

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/799,251 (now U.S. Pat. No. 7,144,586), filed on March 05, 2001.

* * * * *

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 10, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson *et al.* (hereafter “Jackson”) (U.S. Pat. No. 5,807,586) in view of Schlipalius (U.S. Pat. No. 6,132,790).

Jackson (‘586) teaches a dietary supplement composition and method for supplementing the dietary needs of a women comprising once daily administration of a composition comprising a physiologically effective amount of phytoestrogens in combination with mixed carotenoids, such as lycopene (see reference column 1, lines 4-10); (col. 4, line 39 – col. 5, line 14); (col. 6, line 63 – col. 7, line 25) and Table 1 at column 10.

The dietary supplements are formulated to reduce the risk factors of disease, such as iron deficiency anemia, high cholesterol and CHD, osteoporosis and some cancers during the various life stages of a woman (col. 7, lines 25-35).

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The dietary supplements may be formulated as a tablet, capsule, powder, gel or liquid, or dietary bar and are preferably formulated for once daily administration (col. 3, lines 22-26). The phytoestrogens may be administered at levels of less than 25 mg per day (col. 5, lines 6-14).

With regards to the amount of carotenoid claimed, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Jackson teaches the concept of providing a dietary supplement composition having a combination of phytoestrogens with mixed carotenoids. Jackson, as noted above, teaches that carotenoids can be included in the composition, of which lycopene is included. Lycopene has been shown to provide for beneficial effects and lycopene intake, for example, has been inversely associated with the risk of (cervical) cancer. See col. 7, lines 4-9. Jackson does not teach a mixture of lycopene, phytoene and phytofluene.

Schlupalius ('790) teaches a carotenoid composition comprising carotenoids, such as lycopene, phytoene, phytofluene and mixtures thereof (see col. 3, lines 10-19). The carotenoid composition is derived from natural resources to result in a natural carotenoid composition (col. 1, lines 10-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a mixture of carotenoids, such as a mixture of lycopene, phytoene and phytofluene as taught by Schlipalius within the formulations of Jackson. One would do so with a reasonable expectation of success because Schlipalius teaches such a dietary formulation mixture of carotenoids (*i.e.*, lycopene, phytoene and phytofluene), which are known to provide beneficial antioxidant activity and reduce the risk factors of various diseases, such as heart disease and cancer. The expected result would be an effective method for supplementing the dietary needs of women to result in reduced adverse effects.

* * * * *

Claims 7, 10, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlipalius (U.S. Pat. No. 6,132,790) in view of Gorbach *et al.* (hereafter “Gorbach”) (U.S. Pat. No. 5,498,631) OR Gaynor *et al.* (hereafter “Gaynor”) (U.S. Pat. No. 5,904,924).

Schlipalius ('790) teaches a carotenoid composition comprising carotenoids, such as lycopene, phytoene, phytofluene and mixtures thereof (see col. 3, lines 10-19). The carotenoid composition is derived from natural resources to result in a natural carotenoid composition (col. 1, lines 10-13).

With regards to the amount of carotenoid claimed, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The carotenoid(s) are dispersed in an oil solvent, which can be soybean oil (col. 3, lines 40-44); Example 1. Soybean is an element known to contain isoflavonoids. Such skill is also evident from the reference of Gorbach (see below).

Gorbach ('631) is relied upon for the teaching of a method for treating symptoms of menopause or premenstrual syndrome (PMS) comprising the administration of an effective amount of an isoflavonoid (see Abstract). Gorbach teaches that isoflavonoids, which are constituents of soy beans and other plants, effectively reduce the symptoms of conditions which are caused by reduced or altered levels of endogenous estrogen, e.g., menopause and premenstrual syndrome (PMS). The isoflavonoids, which are present naturally in soy-based and other plant-based foods, are safe and cause no significant side effects (col. 1, lines 30-60).

The dietary product may be administered in medicament form, e.g., mixed with a pharmaceutical carrier to form a tablet, powder or syrup (col. 2, lines 33-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate isoflavonoids, provided in soybean such as taught by Gorbach within the formulations of Schlupalius. One would do so with a reasonable expectation of success because Gorbach teaches therapies for treating menopausal symptoms that comprise administration of soybean, which contain isoflavonoids. Gorbach teaches that the isoflavonoids effectively reduce the symptoms of conditions which are caused by reduced or altered levels of endogenous estrogen, e.g., menopause and premenstrual syndrome (PMS) and teach that the isoflavonoids are safe and cause no significant side effects. The expected result would be an effective method for reducing menopausal and PMS and thus increasing beneficial effects attributed by the formulation therapy.

* * * * *

The teachings of Schlipalius are discussed above.

Gaynor ('924) is relied upon for the teaching of a nutritional powder composition containing soybeans and isoflavones, also known as phytoestrogens. Gaynor teaches that soybeans are composed of two compounds: saponins and isoflavnoids, which are known to enhance immune system activity (see column 2, lines 45-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate isoflavanoids, provided in soybean such as taught by Gaynor within the formulations of Schlipalius. One would do so with a reasonable expectation of success because Gaynor teaches a nutritional composition comprising soybeans as well as phytoestrogens, whereby the soybeans, which contain isoflavanoids provide for beneficial effects, such as enhanced immune system activity. The expected result would be a highly effective formulation and method for providing increased nutritional benefits.

* * * * *

Pertinent Art

▪ **DeMichele *et al.* (U.S. Patent No. 6,013,665):**

DeMichele *et al.* teach methods for enhancing absorption of lipophilic compounds whereby compositions are provided that include phytoestrogens and carotenoids, such as lycopene (see column 7, lines 41-61).

* * * * *

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

hns

April 25, 2008

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